REMARKS

Claims 31-67 have been canceled without prejudice and new claims 31 to 96 have been amended to avoid improper multiple dependencies for multiply dependent claims. Thus, the claims are amended to be in proper United States format. All amendments are fully supported by the International application as originally filed and add no new matter.

Respectfully submitted,

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APPENDIX A
CLAIMS PENDING AS OF ENTRY OF THIS AMENDMENT
(Filed July 31, 2002)

WHAT IS CLAIMED IS:

31. A method of treatment of the human or animal body, said method comprising administering an effective, non-toxic amount of a pharmaceutical composition comprising:

(a) an expression cassette operably linked to (i) a myosin light chain enhancer; (ii) a promoter selected from a myosin heavy chain promoter and a viral promoter; and (iii) a polynucleotide sequence encoding a polypeptide of therapeutic use, or which is expressed to generate a therapeutic product which is an RNA;

(b) a vector comprising said expression cassette; or

(c) a viral strain comprising said expression cassette

combined with a pharmaceutically acceptable carrier or diluent.

32. The method of claim 31, wherein said vector is a plasmid vector or a viral vector.

33. The method of claim 31, wherein said expression cassette is administered as a naked nucleic acid construct.

34. The method of claim 31, wherein said pharmaceutical composition is formulated for intramuscular administration.

35. The method of claim 31, wherein said myosin light chain enhancer is a myosin light chain 1/3 enhancer.

36. The method of claim 31, wherein said myosin heavy chain promoter is a fish myosin heavy chain promoter.

37. The method of claim 36, wherein said fish myosin heavy chain promoter is a carp FG2 myosin heavy chain promoter.

38. The method of claim 36, wherein said myosin heavy chain promoter is a mammalian myosin heavy chain promoter.

39. The method of claim 38, wherein said mammalian myosin heavy chain promoter is a truncated rabbit β-cardiac myosin heavy chain promoter.

40. The method of claim 31, wherein said viral promoter is a cytomegalovirus promoter or a herpes simplex virus promoter.

41. The method of claim 31, wherein said vector further comprises fish or mammalian genomic sequences flanking said expression cassette.

42. The method of claim 31, wherein said vector further comprises viral genomic sequences flanking said expression cassette.

43. The method of claim 31, wherein said polypeptide is α-galactosidase.

44. The method of claim 31, for the treatment of Fabry disease, wherein said polypeptide encoded by said polynucleotide sequence is α-galactosidase.

45. The method of claim 31, wherein said polynucleotide encodes a polypeptide comprising at least one epitope.

46. The method of claim 45, wherein said polypeptide is derived from a pathogenic organism.

47. The method of claim 31, wherein said polypeptide is selected from the group consisting of an enzyme; a blood derivative; a cytokine; a growth factor; a neurotransmitter or a precursor thereof, a synthetic enzyme which generates a neurotransmitter; a trophic factor; an apolipoprotein; a dsytrophin or a minidystrophin; a tumor suppressor; a factor involved in coagulation; a natural or synthetic antibody; or a toxic factor.

48. The method of claim 47, wherein, the cytokine is an interleukin, interferon or TNF.

49. The method of claim 31, wherein said polynucleotide generates a therapeutic product which is an RNA.

50. The method of claim 49, wherein the RNA is an antisense RNA.

51. The method of claim 31, wherein said polynucleotide comprises a heterologous gene.

52. A method for effecting gene therapy in a human or animal, said method comprising introducing:

(a) an expression cassette operably linked to (i) a myosin light chain enhancer; (ii) a promoter selected from a myosin heavy chain promoter and a viral promoter; and (iii) a polynucleotide sequence encoding a polypeptide of therapeutic use in said gene therapy; or

(b) a vector comprising said expression cassette; or

(c) a viral strain comprising said expression cassette;

combined with a pharmaceutically acceptable carrier or diluent.

53. A pharmaceutical composition comprising:

(a) an expression cassette operably linked to (i) a myosin light chain enhancer; (ii) a promoter selected from a myosin heavy chain promoter and a viral promoter and; (iii) a polynucleotide sequence which encodes a polypeptide comprising at least one peptide; or

(b) a vector comprising said expression cassette; or

(c) a viral strain comprising said expression cassette;

combined with a pharmaceutically acceptable carrier or diluent.

54. A method of vaccinating a bird, fish, human or other mammals comprising administering a vaccine composition comprising:

(a) an expression cassette operably linked to (i) a myosin light chain enhancer; (ii) a promoter selected from a myosin heavy chain promoter and a viral promoter and; (iii) a polynucleotide sequence which encodes a polypeptide comprising at least one peptide;

(b) a vector comprising said expression cassette; or

(c) a viral strain comprising said expression cassette;

combined with a pharmaceutically acceptable carrier or diluent to a bird, fish, human or other mammal in need of an amount effective to secure vaccination against a pathogenic organism.

55. The method of claim 56, wherein said polypeptide is derived from a pathogenic organism.

56. A vaccine composition comprising:

(a) an expression cassette operably linked to (i) a myosin light chain enhancer; (ii) a promoter selected from a myosin heavy chain promoter and a viral promoter; and (iii) a polynucleotide sequence which encodes a polypeptide comprising at least one peptide;

(b) a vector comprising said expression cassette; or

(c) a viral strain comprising said expression cassette;

combined with a pharmaceutically acceptable carrier or diluent.

57. The vaccine composition of claim 58, wherein said polypeptide is derived from a pathogenic organism.

58. A method of treatment of the human or animal body, said method comprising administering an effective, non-toxic amount of a pharmaceutical composition comprising:

(a) an expression cassette operably linked to (i) a myosin light chain enhancer; (ii) a promoter selected from a myosin heavy chain promoter and a viral promoter; and (iii) a polynucleotide sequence encoding a polypeptide of therapeutic use which is not a blood coagulation factor, or which is expressed to generate a therapeutic product which is an RNA;

(b) a vector comprising said expression cassette; or

(c) a viral strain comprising said expression cassette;

combined with a pharmaceutically acceptable carrier or diluent.

59. The method of claim 58, wherein said vector is a plasmid vector or a viral vector.

60. The method of claim 58, wherein said expression cassette is administered as a naked nucleic acid construct.

61. The method of claim 58, wherein said pharmaceutical composition is formulated for intramuscular administration.

62. The method of claim 58, wherein said myosin light chain enhancer is a myosin light chain 1/3 enhancer.

63. The method of claim 58, wherein said myosin heavy chain promoter is a fish myosin heavy chain promoter.

64. The method of claim 36, wherein said fish myosin heavy chain promoter is a carp FG2 myosin heavy chain promoter.

65. The method of claim 36, wherein said myosin heavy chain promoter is a mammalian myosin heavy chain promoter.

66. The method of claim 38, wherein said mammalian myosin heavy chain promoter is a truncated rabbit β-cardiac myosin heavy chain promoter.

67. The method of claim 58, wherein said viral promoter is a cytomegalovirus promoter or a herpes simplex virus promoter.

68. The method of claim 58, wherein said vector further comprises fish or mammalian genomic sequences flanking said expression cassette.

69. The method of claim 58, wherein said vector further comprises viral genomic sequences flanking said expression cassette.

70. The method of claim 58, wherein said polypeptide is α-galactosidase.

71. The method of claim 58 for the treatment of Fabry disease, wherein said polypeptide encoded by said polynucleotide sequence is α-galactosidase.

72. The method of claim 58, wherein said polynucleotide encodes a polypeptide comprising at least one epitope.

73. The method of claim 58, wherein said polypeptide is derived from a pathogenic organism.

74. The method of claim 58, wherein said polypeptide is an enzyme; a blood derivative; a cytokine; a growth factor; a neurotransmitter or a precursor thereof; or a synthetic enzyme which generates a neurotransmitter; a trophic factor; an apolipoprotein; a

dystrophin or a minidystrophin; a tumor suppressor; a natural or synthetic antibody; or a toxic factor.

75. The method of claim 58, wherein the cytokine is an interleukin, interferon or TNF.

76. The method of claim 58, wherein said polynucleotide generates a therapeutic product which is an RNA.

77. The method of claim 76, wherein the RNA is an antisense RNA.

78. The method of claim 58, wherein said polynucleotide comprises a heterologous gene.

79. A method for gene therapy in a human or animal, said method comprising introducing:

(a) an expression cassette, operably linked to, (i) a myosin light chain enhancer; (ii) a promoter selected from a myosin heavy chain promoter and a viral promoter; and (iii) a polynucleotide sequence encoding a polypeptide of therapeutic use in gene therapy which is not a blood coagulation factor;

(b) a vector comprising said expression cassette; or

(c) a viral strain comprising said expression cassette.

80. The method of claim 47, wherein the growth factor is IGF-1.

81. The method of claim 47, wherein the trophic factor is BDNF, CNTF, NGF, IGF, GMF, aFGF, bFGF, NT3, or NT5.

82. The method of claim 47, wherein the apolipoprotein is ApoAI or ApoIV.

83. The method of claim 47, wherein the tumor suppressor is the protein encoded by the p53, RB, Rap1a, DCC or k-rev gene.

84. The method of claim 47, wherein the factor involved in coagulation is Factor VII, VIII, or IX.

85. The method of claim 47, wherein the immunoglobulin or part thereof is an Fab or ScFV.

86. The method of claim 47, wherein the toxic factor is diphteria toxin, or a polypeptide encoded by a suicide gene, or a polypeptide encoded by a killer gene.

87. The method of claim 86, wherein said suicide gene is a thymidine kinase or cytosine deaminase gene.

88. The method of claim 86, wherein said killer gene is Grb3-3 or anti-ras ScFv gene.

89. The method of claim 58, wherein the growth factor is IGF-1.

90. The method of claim 58, wherein the trophic factor is BDNF, CNTF, NGF, IGF, GMF, aFGF, bFGF, NT3, or NT5.

91. The method of claim 58, wherein the apolipoprotein is ApoAI or ApoIV.

92. The method of claim 58, wherein the tumor suppressor is the protein encoded by the p53, RB, Rap1a, DCC or k-rev gene.

93. The method of claim 58, wherein the immunoglobulin or part thereof is an Fab or ScFV.

94. The method of claim 58, wherein toxic factor is diphteria toxin, or a polypeptide encoded by a suicide gene, or a polypeptide encoded by a killer gene.

95. The method of claim 94, wherein said suicide gene is a thymidine kinase or cytosine deaminase gene.

96. The method of claim 94, wherein said killer gene is Grb3-3 or anti-ras ScFv gene.